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(54) Title: WATER TREATMENT SYSTEMS FOR FLUID PREPARATION

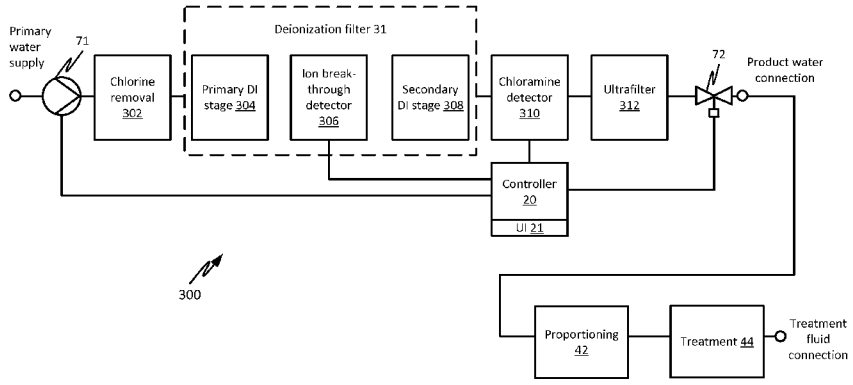

Fig. 1A

(57) Abstract: A water purification component, which may be integrated in a medicament production plant and/or a blood treatment system, removes chloramine and other chlorine compounds and deionizes water. The deionization is selected to be effective for providing product water whose resistivity is sufficiently high to allow chloramine to be detected in the product water if the chloramine removal filtration fails. This allows a chloramine removal filter to be changed based on a predicted exhaustion schedule with the safety of automatic chloramine breakthrough provided.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/13022

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - G01N 27/26; B08B 3/04; A61M 1/16 (2014.01)
USPC - 210/754; 204/416; 73/61.41
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): G01N 27/06, 27/08, 27/10, 27/26, 3/18; B08B 3/04; C02F 1/461, 1/76; B01D 35/143; A61M 1/16; B67D 7/76 (2014.01)
USPC: 210/754, 748.2, 92, 85; 204/416, 400, 228.6; 73/61.41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US Granted, US Applications, EP-A, EP-B, WO, JP, DE-G, DE-A, DE-T, DE-U, GB-A, FR-A); Google; Google Scholar; ProQuest; detect, measure, quantify, analyze, chloramine, monochloramine, dichloramine, nitrogen trichloride, NH2Cl, NHCL2, NCl3, resistivity, conductance, amperometric, temperature, thermostat, thermocouple, thermometer, water, medical, purified, dialysis, NxStage

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0230450 A1 (BURBANK, JH et al.) September 25, 2008; paragraphs [0038], [0060]-[0082], [0099], [0106], [0147]; figure 8a	116, 118-119, 120/116, 120/119
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Y		1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-115, 117, 123-128
Y	US 2012/0216605 A1 (SILVERI, MA) August 30, 2012; paragraphs [0038], [0168], [0169]	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-115, 117, 123-128
Y	US 5,024,766 A (MAHMUD, S) June 18,1991; column 5, lines 20-40	1-15, 32/1-32/15
P, Y	US 2013/0126430 A1 (KENLEY, R et al.) May 23, 2013; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128
A	US 2012/0325696 A1 (BURBANK, JH et al.) December 27, 2012; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128
A	US 2008/0296208 A1 (IKEYAMA, N et al.) December 4, 2008; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128

☒ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 April 2014 (23.04.2011)	11 JUL 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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International application No.
PCT/US14/13022

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/0182263 A1 (BURBANK, JH et al.) July 16, 2009; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128
A	US 7,189,314 B1 (PACE, SJ et al.) March 13, 2007; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128
A	US 5,783,072 A (KENLEY, RS et al.) July 21, 1998; entire document	1-15, 32/1-15, 80-95, 96/93-95, 97-100, 102-119, 120/116, 120/119, 123-128

INTERNATIONAL SEARCH REPORT

International application No.
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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 28-31, 33-37, 42-48, 54, 59-61, 63-66, 71-73, 75-79, 101, 121-122, 137-143, 156-166, 171-177, 183, 188, 192, 194-197, and 209-212

3. ☒ Claims Nos.: -***-Please See Directly Above-***-
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-15, 32, 80-100, 102-120, and 123-128 are directed toward a fluid processing system and methods utilizing deionization filter that produces deionized water, for use dialysis treatment, with a resistivity of more than 5 megohm-cm.

Group II: Claims 16-27, 38-41, 49-53, 55-58, 62, 67-70, 74, 129-136, 144-155, 167-170, 178-182, 184-187, 189-191, 193, and 198-208 are directed toward another fluid processing system and methods utilizing a resistivity testing element and a controller to signal a water quality error in response to a detected resistivity of more than 2.5 megohm-cm.

-***-Continued Within the Next Supplemental Box-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 32, 80-100, 102-120, 123-128

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
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-***-Continued from Box No. III: Observations where unity of invention is lacking-***-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a fluid circuit including at least one of a pump and a control valve, the fluid circuit including a replaceable activated carbon filter module configured to remove chloramine from primary water; the fluid circuit connecting a primary deionization filter to the activated carbon filter, the primary deionization filter being configured to remove ions from the water to produce first deionized water with a resistivity of more than 5 megohm-cm; a first resistivity sensor positioned by the fluid circuit at the outlet of the primary deionization filter and adapted for indicating a resistivity of the first deionized water to detect exhaustion of said primary deionization filter, the controller being adapted to generate an exhaustion alarm signal responsively to said resistivity sensor; a secondary deionization filter positioned by the fluid circuit at the outlet of the resistivity sensor from the first filter to provide a backup in the event of exhaustion of the primary deionization filter; a second resistivity sensor and a temperature sensor, positioned by the fluid circuit at the outlet of the secondary deionization filter and configured to apply signals indicating temperature and resistivity to the controller; the controller storing data for converting said signals indicating temperature to data indicating a chloramine level; a proportioning system configured to mix the product water from the fluid circuit with dialysate concentrate to generate dialysate; a medical treatment system connected to said proportioning system and configured to consume said dialysate in performing a dialysis treatment, which are not present in Group II; the special technical features of Group II include a fluid circuit including a replaceable first filter module configured to remove chloramine from primary water and a resistivity testing element positioned downstream of the first filter module such that filtered water from the first filter module is tested thereby to detect for a threshold level of chloramine remaining in the filtered water; the resistivity testing element being adapted to detect resistivity above 2.5 megohm-cm; the first filter module, or a deionization filter upstream or downstream of the first filter module, being adapted to increase a resistivity of the filtered water received by the resistivity testing element, to a level higher than a predefined water quality requirement forming part of a medical treatment standard to which the medical treatment device is subject; the resistivity testing element being adapted to apply to the controller a resistivity signal indicating a resistivity of the filtered water received thereby and the controller being configured to control the flow of filtered water responsively to the resistivity signal such that said controller, in response to a resistivity above a predefined level of more than 2.5 megohm-cm, or a rate of change of a resistivity above a predefined rate, causes said controller to output a signal indicating a water quality error; the controller further being configured to determine a time for replacement of said first filter module; to ensure that only a fraction less than 100 percent of a chloramine removal capacity of the first filter module has been consumed by said time for replacement; and purifying water to produce a product water meeting a predefined water quality requirement that includes a predefined limit on the amount of a specific dissolved species that is weakly conductive and a lower limit on the allowed resistivity of said product water due to all dissolved species which are not present in Group I.

The common technical features of Groups I-II are a fluid processing system adapted for providing purified water for a use in preparing dialysate and having no more than a predefined level of chloramine: a controller and a fluid circuit for controlling of a product water from said fluid circuit; the fluid circuit including a replaceable carbon filter module configured to remove chloramine from primary water; the fluid circuit connecting a primary deionization filter to the carbon filter; a first resistivity sensor positioned by the fluid circuit at the outlet of the primary deionization filter and adapted for indicating a resistivity of the first deionized water to detect exhaustion of said primary deionization filter, the controller being adapted to generate an exhaustion alarm signal responsively to said resistivity sensor; a chloramine detection element; the controller storing data for converting said signals indicating resistivity to data indicating a chloramine level; the controller further being configured to control the flow of product water responsively to said data indicating a chloramine level, the control of flow being effective to prevent the flow of product water in the event of a chloramine level higher than said predefined level; the controller further being configured to generate a signal predicting when said activated carbon filter should be replaced, the predicting being responsive to at least one of a lapsed time since the first filter was replaced, a cumulative volume of water processed by said first filter, a quality of tap water processed thereby; a medical treatment system for use in a dialysis treatment.

-***-Continued Within the Next Supplemental Box-***-

INTERNATIONAL SEARCH REPORT

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-***-Continued from Previous Supplemental Box-***-

These common technical features are disclosed by US 2008/0230450 A1 to Burbank, et al. (hereinafter 'Burbank') in view of US 2012/0216605 A1 (SILVERI). Burbank discloses a fluid processing system adapted for providing purified water for a use in preparing dialysate (preparation of purified water for various uses including dialysis; abstract; paragraph [0060]; claim 1) and having no more than a predefined level of chloramine (by oxidizing chloramines and subsequently, as described below, filtering using a deionizing filter, chloramines can be removed; paragraph [0073]): a controller and a fluid circuit for controlling of a product water from said fluid circuit (the final conductivity/resistivity sensor/alarm 1025 may control the pump; a controller 1090 (a controller) may be connectable to the disposable filter module 910 and configured to stop the pump 1020 (a fluid circuit); the trigger resistivity safety level to cut-off the pump 1020 may be 1 megohm, but may be raised to 2 megohm to allow the use of required temperature compensated resistivity probes (an FDA & AAMI requirement); this does allow use of low cost in-line resistivity probes in the disposable filter module 910; paragraph [0082]); the fluid circuit including a replaceable carbon filter module configured to remove chloramine from primary water (the replaceable (disposable or remanufacturable) filter module 910 contains activated carbon filter 100, which is a well-known adsorption type filter 5; figure 8a; paragraph [0075]); the fluid circuit connecting a primary deionization filter to the carbon filter (the replaceable (disposable or remanufacturable) filter module 910 contains a first stage filter 1007 copper-zinc alloy which is used to subject the water to a reduction/oxidation process to remove ions; followed by activated carbon filter 1005; figure 8a; paragraph [0075]); a first resistivity sensor positioned by the fluid circuit at the outlet of the primary deionization filter and adapted for indicating a resistivity of the first deionized water to detect exhaustion of said primary deionization filter (the resistivity probe 1022 can be included within a single deionizing filter between previous and following deionization stages; paragraph [0075]), the controller being adapted to generate an exhaustion alarm signal responsively to said resistivity sensor (the resistivity probe 1022 detects ion concentration by contact testing of the resistivity of the water; a signal is generated to indicate that this will be the last allowed batch before the system will require the replacement of the replaceable module 910; paragraph [0077]); a contaminate detection element (resistivity sensor 1022 can detect contaminant breakthrough, where chloramines are a contaminant; paragraphs [0073], [0079]); the controller storing data for converting said signals indicating resistivity to data indicating a chloramine level; the controller further being configured to control the flow of product water responsively to said data indicating a conductivity level, the control of flow being effective to prevent the flow of product water in the event of a conductivity level higher than said predefined level (a second, final safeguard resistivity or conductivity test is provided with an audible alarm at 1025 as a back up safety measure; note the final conductivity/resistivity sensor/alarm 1025 may control the pump; a controller 1090 may be connectable to the disposable filter module 910 and configured to stop the pump 1020; the trigger resistivity safety level to cut-off the pump 1020 may be 1 megohm, but may be raised to 2 megohm to allow the use of required temperature compensated (a temperature sensor) resistivity probes (an FDA & AAMI requirement); this does allow use of low cost in-line resistivity probes in the disposable filter module 910; paragraph [0077]); the controller further being configured to generate a signal predicting when said activated carbon filter should be replaced, the predicting being responsive to at least one of a lapsed time since the first filter was replaced (filter modules may be "stamped" with a permitted time of use after a first use when presumably the seal was first broken; this may be enforced in the same manner as discussed with reference to attempted reuse of a filter module after breakthrough was detected; thus, step such an event may be detected at step S60 as well (the controller predicting based on time); paragraph [0106]), a cumulative volume of water processed by said first filter, a quality of tap water processed thereby (the resistivity probe 1022 detects ion concentration by contact testing of the resistivity of the water (the predicting being responsive to a quality of tap water processed thereby); a signal is generated to indicate that this will be the last allowed batch before the system will require the replacement of the replaceable module 910 which includes the activated carbon filter; paragraph [0077]); a medical treatment system for use in a dialysis treatment (when a prescribed quantity of purified water is added to the batch container, the diluted concentrate may form a medicament or infusate such as replacement fluid for hemofiltration or a dialysate for hemodialysis; paragraph [0099]). Burbank does not disclose a chloramine detection element, including a resistivity sensor; the controller storing data for converting said signals indicating resistivity to data indicating a chloramine level. Silveri discloses a chloramine detection element (a sensor system that measures at least one parameter of water, including detection of chloramines; abstract; paragraph [0168]); including a resistivity sensor (the sensor sequentially measures several water parameters, including conductivity (resistivity); paragraph [0035]); the controller storing data for converting said signals indicating resistivity to data indicating a chloramine level (if both species are present, then, in an action block 1032, the system quantifies each species according to the ratio of the first output signal to the second output signal; if both species are not present, the system concludes the method without executing the action block 1032; in certain aspects of the method, the first species comprises free chlorine and the second species comprises chloramine; and the ratio of the first output signal to the second output signal has a value in a first range when the species in the water comprises free chlorine and has a value in a second range when the species in the water comprises chloramine; paragraph [0168]). It would have been obvious to a person of ordinary skill in the art, at the time of the invention, to have modified the fluid processing system, as previously disclosed by Burbank, in order to have provided a chloramine detection element, including a resistivity sensor; the controller storing data for converting said signals indicating resistivity to data indicating a chloramine level, as previously disclosed by Silveri, for the advantage of utilizing the resistivity sensors for detecting contaminants in the filtration system, including chloramines, to ensure a sufficient water quality for dialysis treatments.

Since the common technical features are previously disclosed by Burbank and Silveri, these common features are not special and so Groups I-II lack unity.